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Attachment No. 2

INITIAL STATEMENT OF REASONS**CALIFORNIA CODE OF REGULATIONS**

**TITLE 8: Division 1, Chapter 4, Subchapter 7, Article 109, Section 5197
of the General Industry Safety Orders**

Occupational Exposure to Food Flavorings Containing Diacetyl**SUMMARY**

This proposed rulemaking for a new section in the General Industry Safety Orders was generated in response to concerns of employees, employers, members of the public and members of the California legislature with respect to recently identified respiratory illnesses occupationally associated with food flavorings both in California and nationally.

In July of 2004, the Division of Occupational Safety and Health (Division) and the California Department of Health Services (DHS) [*DHS was absorbed into the new California Department of Public Health (CDPH) on July 1, 2007*] received a report of an employee of a flavor manufacturing company who had been diagnosed with bronchiolitis obliterans. A Cal/OSHA enforcement inspection was conducted at the facility.

Bronchiolitis obliterans is a rare and life-threatening form of obstructive lung disease characterized by significant permanent decreases in pulmonary function. It can progress to the need for a double lung transplant, or to death. Unlike asthma, which is also an obstructive lung disease, the pulmonary function of persons suffering from bronchiolitis obliterans does not improve with application of bronchodilator medications, and is therefore termed a *fixed* obstructive disease.

Exposures to food flavorings generally were not recognized as a possible cause of bronchiolitis obliterans prior to the year 2000. Generally, occupational instances of the disease had been associated with acute reactions following significant overexposures to a variety of industrial chemicals. But in late 2000, the National Institute of Occupational Safety and Health (NIOSH) recognized a new flavoring-related form of the disease that insidiously develops over time without the occurrence of a noticeable acute overexposure. NIOSH first identified a cluster of nine workers with bronchiolitis obliterans at two microwave popcorn plants in the Midwest and associated the chemical *diacetyl* as a marker for the disease. Diacetyl is used as a primary ingredient of many artificial butter flavors such as those used for microwave popcorn, and it is also used as a minor constituent of many other flavorings such as some fruit flavors.

As NIOSH investigated more popcorn plants between 2002 and 2006, employees who had not yet developed bronchiolitis obliterans were found with significant permanent reductions in pulmonary function as measured by pulmonary function tests (spirometry). The risk of abnormal spirometry for these popcorn workers was found by NIOSH to increase with increasing cumulative diacetyl exposure (although the chemical could not be definitively labeled as the causative agent of the lung changes due to insufficient available toxicological data and the presence of other potentially irritating flavoring chemicals).

Meanwhile as NIOSH investigated the popcorn industry, other documented instances of bronchiolitis obliterans or other restrictive lung diseases came to light. Two were reported, respectively, at a potato chip plant and a candy plant where flavoring chemicals were utilized. Two other instances, found at the plants of flavoring manufacturers on the East Coast were reported to NIOSH. In 2004, NIOSH issued an official alert about the connection between workplace exposure to diacetyl and irreversible lung disease. Finally, in April 2006, a potential bronchiolitis obliterans diagnosis of an employee at a second California flavoring manufacturing plant was reported to the Division and the DHS.

A Cal/OSHA enforcement action was taken at the second California flavoring manufacturing plant. More significantly, the Division and DHS concluded as a matter of public health that a special emphasis program targeting the California flavoring manufacturing industry was necessary. The industry was determined to consist of 30 companies. The purpose of this intervention was to ensure the following occurred in each flavor manufacturing company: (1) the health screening of all flavoring employees; (2) the evaluation and characterization of exposure to diacetyl and other substances used in the food flavoring manufacturing process; and (3) implementation of control measures for the identified hazards. Implementation of this special emphasis program, Flavoring Industry Safety and Health Emphasis Program (FISHEP), has involved input from the Division Consultation, DHS, NIOSH, and the National Jewish Medical Research Center (NJMRC) of Denver, Colorado.

On August 18, 2006, the Division received a letter from 23 California legislators (including the chairs of the Assembly and Senate Labor committees and Health committees) requesting that the Division adopt first an emergency and then a permanent standard covering exposure to diacetyl. The letter called for a standard containing a "provisional" Permissible Exposure Limit (PEL) and mandating medical surveillance and respiratory protection. The legislators' requests paralleled those of a petition three weeks earlier to Federal OSHA that had been filed by the United Food and Commercial Workers International Union (UFCW) and International Brotherhood of Teamsters, two unions representing flavoring manufacturing and food manufacturing workers nationally. On August 21, 2006, the Occupational Safety and Health Standards Board (Board) received a petition from the California Labor Federation and the California affiliate of the UFCW that mirrored the requests of the petition that had been received by Federal OSHA. Both petitions were accompanied by a letter of support signed by some 40 scientists and occupational physicians of national repute.

In response to the petition and the letter from the legislators, a public advisory meeting was held on September 28, 2006. In January 2007, the Board granted the California Labor Federation and UFCW petition to the extent that it directed the representative advisory meeting convened the previous September to consider the rulemaking issues raised by the petition. To this end

additional advisory meetings were held by the Division in February, March, May and July 2007. These meetings were well-attended by representatives of broad sectors of the public and important governmental institutions, including Labor, diverse parts of the flavor and food manufacturing industries, public health and respiratory health experts, the DHS, NIOSH and Federal OSHA. The proposed standard discussed below is a culmination of the series of meetings in this public advisory process.

The proposed standard would apply to all flavoring manufacturing facilities that utilize diacetyl or food flavorings containing 1% or greater concentration of diacetyl. A small number of food manufacturing facilities would be covered by the standard if, at the facility, flavorings containing 1% or greater concentration of diacetyl are further processed or used with other food ingredients. All other places of employment would be covered to a limited extent if an employee is diagnosed with a diacetyl related illness.

The proposed new rule requires covered employers to perform an exposure assessment, implement engineering and work practice controls, provide respiratory protection when other controls have not eliminated exposures, provide medical surveillance including health questionnaires and pulmonary function tests, provide medical removal job protection for up to six months, provide specific hazard communication training and labeling, maintain records, make a one-time reporting to the Division, and prepare Material Safety Data Sheets for products containing 0.1% or greater diacetyl concentration by weight.

SPECIFIC PURPOSE AND FACTUAL BASIS OF PROPOSED ACTION

Subsection (a) Scope and Application.

This proposed subsection details the application of the standard. The application is based upon the processes in the flavoring and food manufacturing industries that have been demonstrated to result in exposures to the flavoring constituent, diacetyl. NIOSH and other researchers have found in animal studies that exposure to diacetyl alone can cause rapid irreversible changes to lung tissue that are consistent with the development of fixed obstructive lung disease. NIOSH has found that exposing animals to diacetyl mixed with other flavoring ingredients known to be irritating to the lungs will cause even more damage than exposing animals to diacetyl alone. However, this animal data is limited in its explanatory power so that at this juncture there is insufficient scientific information to categorically label diacetyl as the cause of the bronchiolitis obliterans seen among popcorn and flavor workers.

NIOSH research has shown some evidence of decreased lung function among popcorn workers even at the lowest diacetyl exposures measured during site visits to popcorn plants. Because of interferences and other problems with the experimental sampling method used at the time, it is not possible to determine exactly what concentration of diacetyl was present in the work area during the visits. In addition, it is not certain to what extent the measured exposures represent the exposures that may have contributed to the reduced lung function or development of disease, although the studies demonstrate that working in these operations placed workers at increased risk of reduced lung function and of developing lung disease. The studies performed to date are not sufficient to determine a safe exposure level or permissible exposure limit. It is therefore necessary, in order to protect workers from developing serious lung disease, to base application

of this standard on the presence of diacetyl-containing substances and the types of processes that have shown evidence of contributing to the development of disease.

NIOSH, the Flavor and Extract Manufacturers Association (FEMA) and the petitioning groups agreed during the advisory process that diacetyl has been shown to be a valid marker for flavoring exposures that have caused decreases in employee pulmonary function. NIOSH researcher Kay Kreiss noted that in the NIOSH popcorn plant studies, workers exposed to the highest cumulative diacetyl doses had the greatest risk of having abnormal pulmonary function tests. She further noted that the occurrence of three bronchiolitis obliterans cases at a European diacetyl manufacturing plant significantly pointed to diacetyl as an important agent in causing the disease because exposures to other flavoring agents were limited and low at that plant.

All flavor manufacturers that utilize diacetyl fall within the scope and application of subsection (a)(1). There are currently fewer than 30 flavor manufacturers using diacetyl in California. Food and beverage manufacturers are covered by this subsection if they use pure diacetyl or a food flavoring containing 1% or greater concentration of diacetyl. Most food manufacturers generally utilize flavors containing less than 1% diacetyl (often less than 1/10 of 1%) in contrast to the higher percentage of diacetyl seen at the start of flavor manufacture. Based on discussions with advisory committee members, it is estimated that approximately 10% of the 4700 food manufacturers in California would be covered by this standard. (Employment Development Department 2006 Labor Market Data) In addition, any employer with a known case of diacetyl related lung disease (currently there are no diagnosed cases in California outside of flavor manufacturing) would be covered by this standard.

NIOSH studies in the popcorn and flavoring industries, monitoring results of the FISHEP program at California's flavoring plants and FEMA's studies all associated processes that use 1% or greater concentration of diacetyl containing flavors with detectable and greater employee exposures to diacetyl. Therefore, processes using 1% or greater concentration of diacetyl in the food manufacturing are included in subsection (a)(1) of this proposed rule. This proposed application is necessary because it would apply protective measures to those industries and processes which present the greatest risk to employee pulmonary health.

Subsection (a)(2) would apply this standard in any other place of employment using diacetyl or a flavoring or food product with 1% or greater concentration of diacetyl in which an employee has developed fixed obstructive lung disease. Subsection (a)(3) would require an employer to comply with certain portions of this standard if an employee had been diagnosed with fixed obstructive lung disease for which no cause other than exposure to diacetyl is apparent. These subsections are necessary in order to ensure that employees in other work places that may pose similar hazards to those in subsection (a)(1) are provided with necessary protective measures.

Subsection (b) Definitions.

This proposed subsection contains definitions necessary to make the terms used consistent throughout the standard and to be clear to the regulated public.

Subsection (c) Exposure Assessment and Appendix A.

This proposed subsection would require that covered employers conduct representative assessments using the sampling and analytical methods specified in Appendix A to determine employee exposures to diacetyl. This requirement is necessary so that the effectiveness of exposure control methods that are required by subsequent subsections can be properly gauged by the employer and as one determinant of the necessity for medical surveillance. Depending upon the timing and results of the assessments, an employer may have to initiate exposure control methods, modify the methods utilized, or not have to initiate exposure control methods in the first place. This proposed section also includes requirements for employee notification of monitoring results; such notification is necessary so that employees are apprised of the extent of their exposure to the diacetyl hazard.

Subsection (d) Regulated Area.

This proposed subsection would require employers to establish and demarcate regulated areas where diacetyl containing flavorings are used. This requirement is necessary to limit employee exposure to only authorized employees that are properly protected and trained.

Subsection (e) Engineering Controls and Work Practices.

This proposed subsection is necessary to ensure that employers fully understand the importance of controlling employee exposures to harmful vapors, mists and dusts by effective engineering control measures even when a PEL does not exist. This subsection helps clarify that when an engineering control system such as a ventilation system is not sufficient to control exposures below detectable levels, it shall nonetheless be used to the full extent of its effectiveness, and supplemented by administrative and work practice controls, and, to the extent needed, respiratory protection, in order to prevent harmful exposures. Achieving the lowest feasible level of exposure has added importance since a safe level of exposure to diacetyl has not yet been determined.

This subsection lists two examples of engineering control. These examples help clarify to the regulated public what the proposal means by “engineering controls.” The subsection also gives an example of a work practice control: minimizing the application of heat to processes. Including this example is necessary because, as noted in the discussion above on scope and application, processes utilizing heat greatly increase the risk of exposure. This subsection also requires employers to prohibit work practices that will increase exposure, including dry sweeping of diacetyl-containing materials, using compressed air to remove diacetyl containing materials, and opening of pressurized vessels until they have been depressurized. It also requires that employers implement procedures to protect employees from exposures due to a spill or other uncontrolled release of diacetyl or diacetyl containing flavorings.

Finally, this subsection requires that employers document how the engineering and work practice controls that have been implemented actually reduce employee exposures to the lowest feasible level. As mentioned, it is particularly important to bring exposures down as low as feasible for a substance for which no safe level has been determined. This provision is necessary to ensure that employers make the determination that the most effective methods have been adopted and to ensure that this information is available for inspection by the Division.

Subsection (f) Respiratory Protection.

This subsection requires provision of appropriate respirators pursuant to Title 8, Section 5144 where engineering and work practice controls have not eliminated exposures to flavoring constituents. This includes any areas in which diacetyl-containing powders are present, any other areas in which there are processes utilizing diacetyl that are not enclosed, and during spill clean up. This requirement is necessary because no safe limit for diacetyl has been determined and to clarify to the regulated public that the requirements of Section 5144 for respiratory protection programs apply whenever respirators are utilized in the workplace.

This subsection also requires provision of respirators upon request to employees working in or adjacent to a regulated area or in an area in which there is an enclosed process. This requirement is necessary to ensure that employees who may be unusually sensitive to flavorings or who may work in an area that has not been assessed or who may occasionally enter areas where they may be exposed can be protected by respirators. This use is to be considered mandatory use for the purpose of the requirements of Section 5144.

Subsection (g) Medical Surveillance.

This subsection requires medical surveillance for certain employees based on specific criteria. Medical surveillance is necessary because occupational investigations conducted in several states by NIOSH and others have identified fixed obstructive lung disease, respiratory symptoms, and spirometry abnormalities among employees in jobs involving exposure to diacetyl and food flavorings containing diacetyl. Medical surveillance is necessary to detect respiratory system effects at an early stage, when it may be possible to intervene to prevent permanent lung damage in individual employees and to protect other employees who may be at risk.

DHS and NIOSH collaborated on a cross-sectional study analyzing medical surveillance data collected from 2004 to 2008 on 584 workers from 19 California flavor-manufacturing companies; this group represents a majority of exposed workers and companies in the industry statewide. The study (not yet published) found that flavoring workers were at increased risk of severe airway obstruction as indicated by spirometry testing. To date, eight of the workers in the study have been identified by health care providers to have either bronchiolitis obliterans or fixed obstructive lung disease. Added to the 2004 index case, this brings the total number of flavorings-related lung disease cases identified in California to nine. Review of supplemental data submitted through the FISHEP medical surveillance effort has identified other abnormal spirometric results, including some declines in spirometric function over time. The significance of these declines is still being reviewed, but in one instance an asymptomatic flavoring worker had a significant, rapid decline in lung function (FEV₁ decline great than 1 liter) over a five-month period. This worker was subsequently diagnosed with mild fixed airways obstruction, thus further highlighting the need for routine, ongoing medical surveillance of diacetyl-exposed workers.

Subsection (g)(1) General.

This subsection requires employers to establish, implement and maintain a medical surveillance program. The subsection describes the qualifications and responsibilities of the physician who will oversee the program. It also describes the necessary components and characteristics of the medical surveillance program. These requirements are necessary so that effective medical

surveillance will take place in the workplaces within the scope of this proposed regulation. The overall necessity for a medical surveillance program is described in the immediately preceding paragraph which introduces subsection (g) and applies to all of the subsection's parts.

Subsection (g)(2)

Subsection (g)(2) identifies the employees who are required to be included in the medical surveillance program. These employees include those who enter regulated areas or areas with open processes or detectable levels of diacetyl for any portion of 30 days in a 12 month period. This is necessary to ensure that employees who have chronic exposures to diacetyl are included in medical surveillance and reflects the experience of NIOSH and FISHEP that employees who regularly work in areas where airborne diacetyl is present are at increased risk of developing lung disease. Employees who experience signs or symptoms of diacetyl related disease are also required to be included in medical surveillance. This is necessary to enable the early detection of disease in order to mitigate its course. Medical surveillance must also be provided to employees who have been exposed to an uncontrolled release of diacetyl. This is necessary because there is evidence that single high exposures to diacetyl may initiate lung disease.

Subsection (g)(3) Initial/Baseline Medical Evaluation and Appendix B1

Subsection (g)(3) establishes requirements for initial medical evaluations. This subsection recommends the provision of the initial evaluation prior to an employee's assignment to an area where diacetyl exposure may occur. It further requires that it be provided no later than the 30th day that an employee works in an area that requires medical surveillance. This is necessary to ensure that a baseline is established as early as possible in order to enable the early detection of disease. This subsection also requires that a medical evaluation be provided as soon as possible, and no later than 10 days following either an employee developing signs and symptoms of disease or an employee being exposed to an uncontrolled release.

Subsection (g)(3) also lists the required components of an initial medical evaluation. The initial evaluation must include a detailed occupational history; this is required because such a personal history is necessary for occupational physicians to make appropriate and valid medical determinations. The evaluation must include a specific health questionnaire that is at least as comprehensive as the questionnaire contained in Appendix B1, Flavor Worker Initial Questionnaire. Such equivalency is necessary because this questionnaire has been determined by the DHS and NIOSH to provide necessary information for occupational physicians to make appropriate and valid medical determinations. Employees must be made familiar with signs and symptoms associated with exposure to the disease prior to filling out the questionnaire so that they can provide the most accurate information possible for evaluation by the medical professional. Subsection (g)(3) requires the administration of pulmonary function tests (PFTs) which are necessary because abnormal spirometry findings indicate a need for further medical evaluation and clinical decision-making regarding diagnosis and need for work restrictions.

Subsection (g)(3) also requires a PFT be performed and evaluated pursuant to guidelines elaborated by the American Thoracic Society (ATS) or equivalent and that the technicians performing the tests have successfully completed a certified course in spirometry and demonstrated knowledge of proper techniques including those for coaching test subjects. These requirements are necessary because: (1) PFTs are part of the accepted diagnostic methodology for fixed obstructive lung diseases, including bronchiolitis obliterans, and PFTs can identify

abnormal lung changes before they have become severe; (2) implementing the guidelines of the ATS ensures that PFTs will generate accurate information, as these highly technical tests can easily yield inaccurate results when poor procedures are followed; (3) the accuracy of the tests depend on the abilities of the test administrators. In regard to this last point, DHS, in consultation with a NIOSH consultant and expert, evaluated the PFT results obtained by several California private medical providers during the FISHEP program and found that many were quite inadequate. DHS attributes this inadequacy in part to the fact that most medical providers offering spirometry are familiar with utilization of PFTs only as a pass/fail test for individual respirator approvals and not as a means of identifying and tracking the progressive loss of lung function that has been documented among flavoring exposed workers.

This subsection's requirement for initial medical evaluation also includes a requirement [(g)(3)(D)] for additional medical tests deemed appropriate by the evaluating PLHCP. The additional test requirement is particularly important and necessary for the diagnosis of bronchiolitis obliterans and other fixed obstructive lung disease conditions. A single PFT may indicate a temporary lung function decrease due to a contagious illness or an allergy, so a second PFT may be necessary. More important is a bronchodilator challenge test. After inhaling a bronchodilator, a test subject whose first PFT has indicated a decrease in lung function is given a second PFT. If improvement in lung function is observed, a diagnosis of asthma (non-fixed obstructive disease) is likely, while a diagnosis of fixed obstructive disease can generally be ruled out. The bronchodilator challenge test is one crucial step among several leading to a diagnosis of bronchiolitis obliterans.

Subsection (g)(4) Follow up Evaluations.

Subsection (g)(4) requires follow up spirometry tests for employees identified under subsection (g)(1) at least every six months, when the evaluating PLHCP finds them necessary or when employees develop signs and symptoms consistent with flavoring exposures. These requirements are necessary because severe flavoring associated obstructive lung disease may develop in as short as six months according to NIOSH findings in the popcorn industry and in the California flavor manufacturing industry. For example, one worker at a California flavor company had a normal PFT when NIOSH researchers first did an evaluation. Six months later a follow up PFT registered a large pulmonary function deficit. NIOSH also found that symptoms sometimes can provide a warning of decreased lung function; a follow up test in such circumstances can provide the information necessary so a worker can be removed from exposure and any further potential decline in lung function therefore prevented. For the same reasons, and for the reasons described in the discussion of subsection (g)(3) above, this subsection also requires administration of a questionnaire that is the equivalent of the Flavor Worker Follow-Up Questionnaire in Appendix B2. Subsection (g)(4) also provides for necessary follow-up evaluations for employees in the medical surveillance program as a result of a diacetyl spill, leak or process upset.

Subsection (g)(5) Termination of Employment or Reassignment.

This subsection specifies that medical evaluations be provided when an employee terminates employment or is reassigned to work that does not require medical surveillance. This is necessary to ensure that any disease that has developed since the previous evaluation is detected, and appropriate follow-up recommendations can be provided to the employee. For employees who are reassigned to employment with the same employer, medical surveillance is required to

be provided for the twelve-month period following cessation of exposure to diacetyl. This is necessary because there may be a delay in the development of disease after exposure has ceased.

Subsection (g)(6) Information Provided to the PLHCP.

This subsection specifies what information employers must provide to the PLHCP who will be performing the evaluations and tests required by subsections (g)(3) through (g)(5). The information required includes a copy of the proposed rule, a copy of the CDPH Guidelines for medical surveillance, a description of employee duties as they relate to employee exposure to diacetyl, air monitoring data representative of that exposure, a description of any personal protective equipment utilized, all appendixes to this standard, a listing of any diacetyl spills, leaks, or process upsets to which the employee has been exposed and, finally, any information from previous employment related medical evaluations. For respirator medical evaluations, the employer is also required to provide the information required by Section 5144(e)(5). PLHCPs need this information so that they can make appropriate and valid medical determinations.

Subsection (g)(7) Change of PLHCP.

This subsection requires that when the employer changes supervising physicians all medical surveillance records will be transferred to a new supervising physician. This requirement is necessary to ensure that no medical information important to the surveillance of employees in the program is lost due to administrative error.

Subsection (h) PLHCP Written Opinion.

Subsection (h)(1) specifies that the employer obtain a written opinion from the examining PLHCP that details the PLHCP's opinion of whether there are:

- a) any limitations on respirator use, in accordance with Section 5144(e)(6),
- b) any recommended limitations on the examined employee's exposure to diacetyl or other flavoring substances or ingredients or the use of personal protective equipment,
- c) any medical conditions that may have resulted from exposure to diacetyl or other flavoring constituents,
- d) a need for further evaluation, and
- e) a need for employees to be provided a modified work assignment or removed from a particular job assignment. Subsection (h)(1)(E) further requires that the written opinion affirm that the employee has been informed by the PLHCP of any medical condition that may be aggravated by flavoring exposures.

These requirements are necessary to ensure that the employer is made aware of any relevant medical findings that would make workplace adjustments necessary in regard to protecting the affected employee.

Subsection (h)(2) requires the employer to provide a copy of the entire written opinion to the affected employee within five calendar days of its receipt. The employer is further required to provide a notice of the employee's right to seek a second medical opinion regarding issues of medical removal. This is necessary to ensure that the affected employee is made aware of the medical findings in a timely fashion and to ensure that the employee is aware of his or her right to seek a second medical opinion.

Subsection (i) Medical Removal.

Subsection (i)(1) specifies that when an evaluating PLHCP recommends an employee be restricted from the employee's normal work, the employee will be transferred to comparable work that would not involve exposure to diacetyl or other potentially hazardous flavoring constituents (if such work is available) without loss of pay or benefits, for up to six months. If comparable work is unavailable, the employer must still maintain the employee's pay and benefits until whichever comes first: such work becomes available, or the employee is medically determined to be able to return to original job status, or the employee is determined to be unable to return to work involving exposure to diacetyl or other potentially hazardous flavoring constituents, or until six months elapses. When an employee is medically removed, competent medical counseling must be provided to the employee.

Subsections (i)(2) and (i)(3) specify offsets in the amounts employers would have to pay to employees who have been designated for medical removal when no comparable work is available. These subsections allow the employer to avoid overpayments when medically removed employees receive workers compensation or other payments. These subsections are identical to the provisions of other regulations that have medical removal sections.

Subsection (i)(4) specifies the provisions for a multiple physician review if the initial physician recommendation is disputed by the employee. The additional review procedures include notification of the employee and specified timeframes along with procedures to follow when the additional review has a differing recommendation.

The provisions of subsection (i) are necessary to ensure that employees who are determined to be at risk of serious lung disease due to exposure to diacetyl or other flavoring ingredients are removed from exposure that might otherwise result in the progression of disease. The provisions protect employee rights by providing for the possibility of an employee returning to original job status if the pulmonary decline proves to be transitory or reversible, and they ensure that employees are kept fully informed with appropriate medical information that allows employees to be cognizant of the risk of continued exposure to diacetyl or other flavoring constituents. The six month time frame is necessary because it sometimes takes up to that amount of time for the series of medical tests to be performed that are necessary to determine if a pulmonary function decline is in fact permanent and irreversible. This protection is also necessary to ensure that economic considerations do not prevent the employee from actively participating in medical surveillance procedures, which are necessary to ensure that disease is detected at an early stage.

Subsection (j) Information, Training and Labeling of Flavorings.

For those occupations with flavoring exposures this subsection makes specific how the information, training and labeling requirements already contained in Sections 3203, 5144 and 5194 of these Orders need to be implemented for effective compliance with those standards.

Subsection (j)(1)(A) requires that all employees in a workplace that is covered by this standard receive awareness training that includes basic information on the health effects of exposure to diacetyl, the location and description of processes that use diacetyl or diacetyl-containing flavorings, the location of regulated areas, and the fact that employees are prohibited from entering those areas unless they are protected as required by this section. This is necessary to ensure that all employees avoid inadvertent exposures to diacetyl.

Subsection (j)(1)(B) requires initial and annual training for employees who work in areas where diacetyl or diacetyl-containing flavorings are present. Annual training is necessary so that employees do not forget the potential for diacetyl and other flavoring constituents to cause severe and irreversible lung changes. Additional training is also required when there are changes to production, work methods or controls that may affect the employee's exposure. This is necessary so that the employee will be informed of how to use these new methods or control measures so that inadvertent exposures are prevented.

The training is required to include the nature of the operations that may result in exposure to diacetyl or flavorings, the results of exposure assessments including exposure monitoring, the limitations of exposure monitoring techniques to detect exposures to diacetyl containing powders and mists, a description of the medical surveillance program, the employer's control measures, including the means of demarcating regulated areas and the requirements for entry into regulated areas. The training must also include the information in Appendix C that explains the signs and symptoms associated with exposure to diacetyl. Employees who enter regulated areas or who use respirators are also required to receive the training required by Section 5144. These training requirements are necessary to ensure that employees are fully informed of the hazards associated with exposure to diacetyl and flavorings, are aware of how they can participate in medical surveillance, and are able to fully benefit from the employer's control measures.

Subsection (j)(2) requires all containers of diacetyl be labeled with a specific warning about the severe respiratory hazard associated with this chemical. This subsection also permits the use of placards, signs, or similar means to provide this warning for stationary process containers.

This requirement is essential because many Material Safety Data Sheets (MSDS) for diacetyl currently do not include any information about the possibility of lung damage and because the label provides an immediate warning to employees in areas where diacetyl or diacetyl-containing flavorings are used. This requirement therefore clarifies for employers how to prepare labeling with adequate warnings for diacetyl containing flavors.

Subsection (k) Recordkeeping and Reporting Appendix D.

Subsection (k)(1) establishes record keeping requirements for this section. It requires medical and exposure records, including records of entry into regulated areas, be maintained in accordance with Section 3204. The subsection establishes a three-year retention period for training records. Records of assessment of ventilation systems are required to be created and maintained in accordance with Section 5143. This subsection is necessary, first, to remind employers that the existing requirements for retention of and access to all medical and exposure records apply to such records pertaining to flavoring exposures. Second, it is necessary that these other types of records be maintained and be available for a reasonable period of time as these records provide information relevant to employee's exposures and possible development of irreversible lung damage. Such records might be utilized by employees or employers in the workers' compensation arena or by either group as a means of assessing the adequacy of an employer's efforts to reduce flavoring exposures.

Within 24 hours of becoming aware of any flavor-related diagnosis of fixed obstructive lung disease, subsection (k)(2) requires the employer to report such diagnosis to the Division. This is

necessary so that the Division may conduct a timely investigation to determine if additional control measures are necessary in the establishment.

Subsection (k)(3) requires that employers report any product or process containing a 1% or greater concentration of diacetyl to the Division using the questionnaire in Appendix D, which will be a form available for electronic submission directly to the Division on its website. This report is necessary for the Division to utilize the information to determine the extent of use of diacetyl and diacetyl-containing flavorings in the food industry and prioritize which manufacturers should be inspected to assess compliance with this standard. In its web-based form, Appendix D will prompt employers to answer questions number 7 through 21 (concerning the employer's manufacturing processes that utilize diacetyl or diacetyl-containing flavorings) as many times as necessary for the details of each distinct diacetyl related process run by the employer to be recorded. The exception to this subsection relieves employers who have already participated with the Division's FISHEP program from the responsibility to complete this report, since the Division already has this information.

Subsection (l) Material Safety Data Sheet Preparation.

This subsection requires that Material Safety Data Sheet (MSDS) record the percentage range of diacetyl and all appropriate hazard warnings and other toxicology and health effect information whenever a flavoring or food product contains 0.1% diacetyl or more. This section is necessary to clarify to employers that this information must be included on MSDS for products with 0.1 percent or more diacetyl. Many employers, including many California flavoring manufacturers have been shipping products with less than 1% diacetyl, but more than 0.1%, without listing the presence, percentage or health effects of the diacetyl in the product.

These omissions stem from a common misreading of the MSDS preparation requirements of Title 8, Section 5194(g). That section sets a 1% criterion for reporting the presence on an MSDS of a chemical that is not a carcinogen. However, MSDS preparers have missed the implication of subsection (g)(5) of that standard which states "If the manufacturer, importer, or employer become aware of any significant information regarding the hazards of a substance, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within three months." Information developed by NIOSH, FEMA and NJMRC between the year 2000 and the present provide a powerful indication that diacetyl may cause serious lung harm at concentrations below 1%. This information about diacetyl's toxicity also triggers Section 5194 subsection (g)(2)(A)(3)(b) which requires listing ingredients composing less than 1% of a mixture when that ingredient could present a health hazard to employees.

Subsection (l) also requires that the MSDS for a flavoring or product containing 0.1 percent or greater diacetyl state either the actual percentage of diacetyl in the product or state one of five percentage ranges of diacetyl in the material. This is necessary so that employers and employees are aware of the concentration of diacetyl and that employers may choose materials that have a lower concentration of diacetyl as one means of reducing employee exposures.

DOCUMENTS RELIED UPON

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Occupational Safety and Health Standards Board Decision dated January 18, 2007, in the matter of Petition File No. 486 by Art Pulaski, California Labor Federation and George Landers, United Food and Commercial Workers, Western States Council

Division Evaluation Report of Petition File No. 486, dated November 27, 2006

Petition dated August 21, 2006, submitted by Art Pulaski, California Labor Federation and George Landers, United Food and Commercial Workers, Western States Council, to the Occupational Safety and Health Standards Board

These documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the Standards Board Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, California.

DOCUMENTS INCORPORATED BY REFERENCE

California Department of Public Health. Medical Surveillance for Flavorings-Related Lung Disease Among Flavor Manufacturing Workers in California, August 2007.

Hankinson, JL, Odencrantz, JR, Fedan, KB (1999). Spirometric Reference Values from a Sample of the General U.S. Population, *Am J Respir Crit Care Med* 159,179-187

“ATS/ERS Task Force: Standardisation of Lung Function Testing,” a five part series, *Eur Respir J* 2005; 26: 153–161, 319-338, 511-522, 720-735, 948-968.

Sampling and Analytical Methods for Acetoin and Diacetyl, Methods ID 1012 and ID 1013, Federal OSHA Methods Development Team, OSHA Salt Lake Technical Center, Sandy, Utah, 2008.

These documents are too cumbersome or impractical to publish in Title 8. Therefore, it is proposed to incorporate the documents by reference. Copies of these documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the Standards Board Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, California.

REASONABLE ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES

No reasonable alternatives were identified by the Board and no reasonable alternatives identified by the Board or otherwise brought to its attention would lessen the impact on small businesses.

FINDING OF NECESSITY FOR REPORT REQUIREMENT

The Board finds that it is necessary for the health, safety and welfare of the people of the state that this standard's reporting requirements apply to business. Subsection (k) of this standard requires reporting of a diagnosis of flavor-related fixed obstructive lung disease to the Chief of the Division because it is necessary for the Division to be made aware of such a diagnosis in order for it to ensure that proper employee safeguards are put in place as soon as possible. Subsection (k) of this standard also further requires certain employers using concentrated forms of diacetyl to complete and submit to the Division a questionnaire found in Appendix D. This questionnaire, which is to be completed and submitted only one time, is necessary for the Division to be sufficiently informed to be able to protect the employees of such facilities.

SPECIFIC TECHNOLOGY OR EQUIPMENT

This proposal will not mandate the use of specific technologies or equipment.

COST ESTIMATES OF PROPOSED ACTION

Costs or Savings to State Agencies

No costs or savings to state agencies will result as a consequence of the proposed action.

Impact on Housing Costs

The Board has made an initial determination that this proposal will not significantly affect housing costs.

Impact on Businesses

The Board has made a determination that this proposal will not result in a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Cost Impact on Private Persons or Businesses

The proposed standard will have a cost impact on flavoring manufacturing companies in California. Currently, there are fewer than 30 such flavor manufacturers employing in total about 750 employees. A small number, (estimated less than 10% per advisory committee discussions) of the approximately 4,700 California food manufacturers (EDD, 2006) are anticipated to utilize diacetyl containing flavorings at concentrations at or above 1% or at whose establishments employees develop fixed obstructive lung disease due to occupational exposures may be affected by the proposed standard. Currently, there have been no diacetyl related fixed obstructive lung cases identified at California workplaces other than at flavoring manufacturers, and there is no data on how many, if any, food manufacturers utilize diacetyl flavorings at the trigger concentration.

Existing California Title 8 standards require exposure assessments, utilization of engineering and work practice controls for hazardous exposures, and provision of personal protective equipment. Based on FISHEP cost estimate data, the proposed standard is expected to add a small additional increase to those existing costs to provide the specified number of exposure assessments at \$300 annually, engineering control plan elements at \$2,500 in initial costs and respiratory protection at \$200 annually. Therefore an estimate of \$3,000 initially and \$500 annually per employee in added new costs for these requirements is anticipated.

The proposed rule may result in a small increase in training costs in order for employers to properly train their employees in accordance with the training requirements in the proposal. Employers are already required to conduct periodic training as required by Title 8 Section 3203 (Injury and Illness Prevention Programs), and training on hazardous substances as required by Title 8 Section 5194 (Hazard Communication). The proposed training details can easily be incorporated into employers' existing training programs with a minimum of cost.

The proposed rule's requirement for medical surveillance will add new costs, about \$200 per exposed employee per annum based upon the experience of flavoring manufacturers in the FISHEP program. The proposed rule's medical removal benefit will add small unspecified additional costs to businesses for up to six months only when an employee has either developed or is suspected of being at risk for developing fixed obstructive lung disease. This additional cost will vary; it could be a few cents an hour to make up the difference in pay between job classifications, or it could be as much as the full pay of an employee for whom no alternative work is available. The medical removal requirement will not lead to significant costs for employers. Thus far in the California flavor manufacturing industry, less than five percent of workers undergoing medical surveillance have met criteria to be considered for medical removal.

Overall, the total additional costs for flavor manufacturers are estimated to be \$3,200 initially and \$700 annually per employee which averages out to be less than \$65,000 per facility in initial costs and \$15,000 on an annual basis. For the fewer than 30 flavoring manufacturers in California, there would be no additional initial costs over the total estimated \$2 million already incurred, and annual costs would total less than \$500,000. This estimate is based upon informal communications between the Division and employers in the FISHEP program. This estimate does not take into account cost savings from reduced workers compensation costs due to the reduced number of illnesses resulting from implementation of engineering controls, work

practice controls and respiratory protection requirements. It is expected that similar initial and continuing costs would be experienced by the small percentage of food manufacturing companies that will be impacted by this proposed regulation.

Costs or Savings in Federal Funding to the State

The proposal will not result in costs or savings in federal funding to the state.

Costs or Savings to Local Agencies or School Districts Required to be Reimbursed

No costs to local agencies or school districts are required to be reimbursed. See explanation under "Determination of Mandate."

Other Nondiscretionary Costs or Savings Imposed on Local Agencies

This proposal does not impose nondiscretionary costs or savings on local agencies.

DETERMINATION OF MANDATE

The Occupational Safety and Health Standards Board has determined that the proposed standard does not impose a local mandate. Therefore, reimbursement by the state is not required pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the proposed amendment will not require local agencies or school districts to incur additional costs in complying with the proposal. Furthermore, the standard does not constitute a "new program or higher level of service of an existing program within the meaning of Section 6 of Article XIII B of the California Constitution."

The California Supreme Court has established that a "program" within the meaning of Section 6 of Article XIII B of the California Constitution is one which carries out the governmental function of providing services to the public, or which, to implement a state policy, imposes unique requirements on local governments and does not apply generally to all residents and entities in the state. (County of Los Angeles v. State of California (1987) 43 Cal.3d 46.)

The proposed standard does not require local agencies to carry out the governmental function of providing services to the public. Rather, the standard requires local agencies to take certain steps to ensure the safety and health of their own employees only. Moreover, the proposed standard does not in any way require local agencies to administer the California Occupational Safety and Health program. (See City of Anaheim v. State of California (1987) 189 Cal.App.3d 1478.)

The proposed standard does not impose unique requirements on local governments. All state, local and private employers will be required to comply with the prescribed standard.

EFFECT ON SMALL BUSINESSES

The Board has determined that the proposed amendments may affect small businesses.

ASSESSMENT

The adoption of the proposed standard will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses or create or expand businesses in the State of California.

ALTERNATIVES THAT WOULD AFFECT PRIVATE PERSONS

No reasonable alternatives have been identified by the Board or have otherwise been identified and brought to its attention that would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.